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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,652	01/23/2004	Robert Edward Auer	14487	8546

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EXAMINER

VALENTIN, JUAN D

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,652	Applicant(s) AUER ET AL.	
	Examiner Juan D. Valentin II	Art Unit 2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/23/2004, 07/11/2005, 10/28/2005.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 claims that at least one laser excites a maximum number of dyes, but has not defined what the maximum number is, therefore is it the position of the number that no matter how many dyes are excited by a laser, it reads on the limitation “exciting a maximum number of dyes”. Further, claim 14 goes on to claim that the number of fluorescence detectors equals the maximum number of dyes. This statement confuses the examiner; it is unclear whether the applicant is referring to the total number of excitable dyes located within the particle under test? Or the total number of dyes excitable by each laser? A maximum could be anything defined by the user, therefore in the instant rejection, it is deemed that Martin reads on said claimed limitations.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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2. The claimed invention is directed to non-statutory subject matter. With regards to claims 16 & 17, merely identifying; determining; devising; evaluating; detecting; assigning; etc... is not sufficient to constitute a tangible result, since the outcome of the method steps has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application is realized. See OG Notices: 22 November 2005, "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility".

Practical application that produces a useful, concrete, and tangible result under Section IV determines whether the claimed invention complies with the subject matter eligibility requirement of 35 U.S.C. Sec. 101, sentence 3, in the OG Notice from 22 November 2005 states 'In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible, and concrete."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 7-16, 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (USPN '796, hereinafter Martin) in view of Hansen et al. (USPN '412, hereinafter Hansen).

Claims 1, 8-15, 19

Martin in conjunction with Fig. 1, discloses a system for measuring the irradiance of a fluorescently labeled particle 20,22 comprising a cytometric flow chamber 16 having a flow path for passage of the fluorescently labeled particle 20,22, a plurality of excitation light sources (claim 11, laser, col. 4, lines 4-5) 10,12, each emitting a beam of light 18,50 incident on the cytometric flow chamber 16, a plurality of scatter detectors (claim 8) 32,34 in optical communication with the flow path of the cytometric flow chamber 16, each configured to detect light 36 from only one of the plurality of excitation light sources 10,12 and arranged so as to detect scattered light 36 from the fluorescently labeled particle 20 as it passes through the flow path of the cytometric flow chamber 16 (col. 2, lines 43-56, col. 2, lines 62-65, col. 3, line 61-col. 4, line 8).

Martin further discloses a trigger (gate signal generators 37,38) connected to the plurality of scatter detectors 32,34 that trigger (generate) a signal when scattered light 36 incident on one of the scatter detectors 32. It is noted that any substantial scattering signal received from the light scatter detectors 32,34 and sent to the gate signal generator is deemed to exceed a predetermined threshold value whether it be any signal above zero or some other optimal scatter light detection value which triggers the gate signal generator to send signals to the gate signal processor (col. 2, line 62-col. 3, line 13, col. 4, line 21-col. 5, line 13).

Martin discloses at least one fluorescence detector (claim 9) 24,26 to receive the emissions collected by the collection optics and generate an output, the at least one fluorescence detector 24,26 being configured to respond only to a discrete number of wavelength bands (col. 2, lines 50-61, col. 4, lines 4-20 & 40-55), and at least one integrator 38,40 connected to the

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trigger (gate signal generator) and the at least one fluorescence detector 24,26, for recording the output of the at least one fluorescence detector 24,26 in response to a signal from the trigger 37,38 (col. 4, line 32-col. 5, line 14).

Martin substantially discloses the claimed invention, but fails to disclose collection optics and spectral filters in optical communication with the flow path of the cytometric flow chamber to collect emissions (photomultiplier) from the fluorescently labeled particle and photodiodes (photo sensors) to detect scattered light. While using collection optics and spectral filters to couple light of specific wavelengths into detectors (photomultiplier tubes) and using photodiodes to detect scattered light is well known to someone of ordinary skill in the art at the time of the claimed invention, Hansen shows that it is known to provide collection optics to couple fluorescent light emitted by particles into photomultiplier tubes as well as photosensors to detect scattered light (claims 8-10, Fig. 1, refs. 107, 111, 112, 113, col. 4, lines 32-66) for an fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the fluorescence collection optics of Hansen for the purposes of providing efficient couple of fluorescence emitted by particles under test within the flow cytometry chamber.

For the further limitation in claim 14 reciting that at least one laser excites "a maximum number of dyes", applicant has not defined within the claim what "a maximum number of dyes" is, so for the purposes of this rejection, examiner notes that the maximum numbers of dyes excited by each laser be equal to one, therefore satisfying the claimed limitation. Further, Martin discloses a fluorescence detector for every laser used, in which each laser excites one dye, therefore meaning that the number of fluorescence detectors equals the number of detected dyes.

Claims 2, 3

Martin discloses the use of distinct light source and detector pairs for the purposes of illuminating and detecting separate wavelengths of light, as well as emitted fluorescents which are wavelength specific depending on the particular dye(s) used (col. 2, lines 50-61, col. 4, lines 4-20). It would have been obvious to someone of ordinary skill in the art at the time of the claimed invention was made to add at least one more light source and detector pair for the purposes of providing detection of an additional/different fluorescent dye (fluorochrome), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

Claim 7

Martin substantially discloses the claimed invention, but fails to disclose wherein the at least two excitation light sources are focused to overlap in the flow path of the flow chamber. Hansen shows that it is known to provide two excitation light sources are focused to overlap in the flow path of the flow chamber (Fig. 1) for an fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the overlapping excitation beams of Hansen for the purposes of providing cell sensing response of fluorescence to specific types of illumination (Hansen, col. 4, lines 11-15).

Claim 16

The method is suggested by the functions set forth with regards to the apparatus claims 1 & 8-15 as rejected above in view of Martin in view of Hansen.

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4. Claims 4, 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Hansen and further in view of Pinkel (USPN '619).

Claims 4,6

Martin substantially discloses the claimed invention but fails to disclose the use of band pass/spectral filters in combination with the scatter detectors. Pinkel shows that it is known to provide the use of band pass/spectral filters in combination with the scatter detectors (Fig. 1, refs. 18 & 20, col. 2, lines 34-40) for a fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the spectral filters of Pinkel for the purposes of providing spectral filtering of collected scattered light in a flow cytometry system.

5. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Hansen and further in view of Kramer (USPN '634 B2).

Claim 5

Martin substantially discloses the claimed invention but fails to disclose wherein the three excitation light sources are positioned about an excitation light axis, a fiber optic bundle is configured around the excitation light axis, the fiber optic bundle containing three sets of optical fibers, and each set of optical fibers is optically coupled to a different one of the three scatter detectors. Kramer shows that it is known to provide wherein the three excitation light sources are positioned about an excitation light axis, a fiber optic bundle is configured around the excitation light axis, the fiber optic bundle containing three sets of optical fibers, and each set of optical fibers is optically coupled to a different one of the three scatter detectors (col. 7, line 60-

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col. 8, line 59) for a fluorescence detecting flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Martin with the fiber bundle light detection configuration of Kramer for the purposes of providing a relatively small area of respective light-collecting ends by using the optical fibers collection configuration, and further the fibers collect relatively little stray laser light reflecting from various surfaces (e.g. the faces of the optical flow cell, Kramer, col. 11, lines 51-56).

6. Claims 17-18, 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Hansen and further in view of Hoffman (USPN '038).

Claims 17-18

The method is substantially suggested by the functions set forth with regards to the apparatus claims 1 & 8-15 as rejected above in view of Martin in view of Hansen except fails to show assigning any detected fluorescence to dyes known to be excited by the first and second excitation light sources respectively and the number of fluorescence detectors equal to the number of maximum number of dyes stimulated by either first or second light sources. Hoffman shows that it is known to provide assigning any detected fluorescence to dyes known to be excited by the first and second excitation light sources respectively and the number of fluorescence detectors equal to the number of maximum number of dyes stimulated by either first or second light sources (col. 4, line 39-col. 5, line 28) for an multi-laser flow cytometry system. It would have been obvious to combine the device of Hansen with the fluorochrome (fluorescent dye) detection and assignment and fluorescent dye stimulation of Hoffman for the purposes of providing detecting and classifying of multiple fluorescent dyes.

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Claim 20

Hansen substantially teaches the claimed invention except that it fails to show a controller coupled to the fluorescence detection system to control errors/irregularities within the system. Hoffman shows that it is known to provide a controller coupled to the fluorescence detection system to control errors/irregularities within the system (col. 7, lines 16-56, col. 8, lines 55-65, col. 9, lines 18-29) for a multi-laser flow cytometry system. It would have been obvious to someone of ordinary skill in the art to combine the device of Hansen with the controller coupled to the fluorescence detection system to control errors/irregularities of Hoffman for the purposes of providing adjustment of a the actual delay to reduce the error within the predetermines timing tolerance if the actual delay exceeds a predetermined tolerance (Hoffman, col. 9, lines 25-29).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juan D. Valentin II whose telephone number is (571) 272-2433. The examiner can normally be reached on Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Juan D Valentin II
Examiner 2877
JDV
September 16, 2006



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PRIMARY EXAMINER